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By: _____

PATENT
Atty. Docket No.: 018512-005920US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No. 8561
Timothy James Jegla	Examiner: CHERNYSHEV, Olga N.
Application No.: 10/815,297	Technology Center/Art Unit: 1649
Filed: March 31, 2004	
For: KV10.1, A NOVEL VOLTAGE-GATED POTASSIUM CHANNEL FROM HUMAN BRAIN	APPELLANTS' BRIEF UNDER 37 C.F.R. 41.37
Customer No.: 20350	

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Sir:

This brief is filed pursuant to 37 C.F.R. §41.37, following the Notice of Appeal received by the USPTO on September 14, 2007. Also submitted with this brief is authorization to pay the fee as set forth in 37 C.F.R. §41.20(b)(2).

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I. REAL PARTY IN INTEREST

The real party in interest in U.S. Application No. 10/815,297 is Icagen, Inc.

II. RELATED APPEALS AND INTERFERENCES

There are no other pending appeals by Appellant or interferences in which Appellant is involved, the outcome of which would directly affect the decision by the Board of Patent Appeals and Interferences in this pending appeal.

III. STATUS OF THE CLAIMS

Claims 1-38 were originally filed. Subsequently, claims 1-11, 15, and 19-38 were canceled. Claims 12-14 and 16-18 are pending in this application. In the Final Office Action mailed June 11, 2007, the Examiner rejects claims 12-14 and 16-18 under 35 U.S.C. §101, alleging lack of patentable utility. The Examiner also rejects claims 15-20 under 35 U.S.C. §112, first paragraph, alleging lack of enablement based on the utility rejection. The rejections of claims 12-14 and 16-18 are being appealed.

IV. STATUS OF THE AMENDMENTS

No amendment was filed subsequent to the Final Office Action of June 11, 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed subject matter in this appeal relates to a novel polypeptide that comprises an alpha subunit of a Kv potassium channel. Besides its functional features, the claimed polypeptide is further defined by its structural features: it comprises an amino acid sequence that has at least 90% sequence identity to SEQ ID NO:3.

Claim 12

The subject matter claimed in independent claim 12 is an isolated polypeptide, which comprises an alpha subunit of a Kv potassium channel. This polypeptide forms, with at least one additional Kv alpha subunit, a voltage-gating Kv potassium channel. This polypeptide also comprises an amino acid sequence having at least 90% sequence identity to SEQ ID NO:3. Support for this claim can be found in the specification, *e.g.*, in original claim 12, on page 4, lines 10-14, and on page 12, lines 26-33.

VI. GROUNDS OF REJECTION TO BE REVIEWED AND APPEALED

1. The rejection of claims 12-14 and 16-18 for alleged lack of utility.

2. The rejection of claims 12-14 and 16-18 for alleged lack of enablement based on alleged lack of patentable utility.

VII. ARGUMENT

A. The Rejection for Lack of Utility Is Improper

Claims 12-14 and 16-18 stand rejected under 35 U.S.C. §101 because the Examiner alleges that the claimed invention lacks patentable utility. Specifically, the Examiner alleges that, although credible, the asserted utility of this invention is neither specific nor substantial. Appellant respectfully traverses this rejection and argue that the rejection is improper, because the asserted utility is specific for the claimed invention and not generic for a broad class of inventions, and because the asserted utility is ready for "real-world use" and does not require further research.

1. Standard to Assess Utility

According to MPEP §2107, the Examiner should review the claims and the supporting written description to determine whether the utility requirement under 35 U.S.C. §101 is met. No rejection based on lack of utility should be made if an invention has a well-established utility, *i.e.*, a utility that will be immediately appreciated by one of

ordinary skill in the art based on the characteristics of the invention, regardless any such utility has been asserted. Neither should any rejection be made for lack of utility if an applicant has asserted a specific and substantial utility that would be considered credible by one of ordinary skill in the art.

In most cases, an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. §101. MPEP §2107.02 III A. The Court of Customs and Patent Appeals stated in *In re Langer*:

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of §101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

In re Langer, 183 USPQ 288, at 297 (CCPA, 1974, emphasis in original). Thus, to overcome the presumption of sufficient utility as asserted by an applicant, the Examiner must carry the initial burden to make a *prima facie* showing of lack of utility and provide a sufficient evidentiary basis for the conclusion. In other words, the Examiner "must do more than merely question operability--[he] must set forth factual reasons which would lead one skilled in the art to question objective truth of the statement of operability." *In re Gaubert*, 187 USPQ 664, 666 (CCPA 1975).

MPEP §2107.02 IV further states, a detailed explanation should be given for a utility rejection as to why the claimed invention has no specific and substantial asserted utility. Documentary evidence should be provided when possible. Otherwise the Examiner should specifically explain the scientific basis for his factual conclusions.

2. The Asserted Utility Is Specific and Substantial

The present specification provides, for the first time, the cloning of a novel potassium channel subunit, Kv10.1. Pending claims are drawn to an isolated polypeptide, an alpha subunit of a Kv10 potassium channel that belongs to a class of voltage-gated

potassium channels. The instant application asserts a specific and substantial utility of the claimed invention. For example, it is asserted on page 3, lines 2-11, and on page 8, line 14, to page 9, line 7, that Kv10.1 is a subunit of a voltage-gated potassium channel and that the identification of Kv10 subunits allows screening for modulators of voltage-gated potassium channels comprising a Kv10 subunit. Because of the involvement of known Kv channels in regulating various biological processes such as neuronal integration and cell proliferation (see, *e.g.*, page 2, lines 15-23) and also because of the expression pattern of Kv10.1 in the brain, spinal cord, prostate, and retina, it is asserted that these modulators are useful for treating disorders of the central nervous system and for modulating male fertility.

Appellant asserts that the present invention has a specific utility. Specific utility is defined by the MPEP as a utility that is specific to the subject matter claimed. The MPEP explains that applications show sufficient specific utility when applicants disclose a "specific biological activity" and reasonably correlate that activity to a "disease condition." MPEP §§2107.01 and 2107.02. In the present application, Appellant discloses a "disease condition," *i.e.*, altered cytoplasmic potassium concentration, that correlates with a "biological activity," *i.e.*, the opening and closing of the Kv10 channels. This application teaches that the Kv10 channels modulate intracellular potassium concentration. The application further provides methods for identifying modulators of the Kv10 channels capable of modulating potassium influx, *e.g.*, for the treatment of altered biological functions in tissues expressing the Kv10 channels, such as abnormalities found in the retina (*e.g.*, vision disorders) or prostate (*e.g.*, male infertility). Appellant thus submits that the present invention has a specific utility, namely that Kv10 channels can regulate potassium concentrations in the cells of certain tissues, which is clearly specific for the claimed Kv10 channels and not just any ion channels or even any potassium channels.

Appellant also asserts that the present invention has a substantial or "real-world" use. This invention provides Kv10 polypeptides. The application also teaches

that Kv10 channels modulate intracellular potassium concentration in certain tissues, teaches how to assay the function of a Kv10 channel, and teaches how to identify modulators of Kv10 channels. For example, on pages 42-49 of the specification, assays are provided that can be used to screen for inhibitors and activators of Kv10 channels, *e.g.*, assays that involve measuring current, measuring membrane potential, measuring ion flux, or measuring patch-clamp electrophysiology. The present invention therefore has a real-world use in the modulation of intracellular potassium concentration, as well as in the identification of compounds that modulate Kv10 channels and thus can be useful as therapeutic agents for treating diseases related to altered functions in tissues expressing Kv10 channels, such as disorders of the central nervous system.

Finally, Appellant contends that the asserted utility of the present invention is credible, *i.e.*, would be believable to one of skill in the art. An ordinarily skilled artisan, after reading this application, would know (a) how to identify Kv10 potassium channels; (b) how to identify modulators of Kv10 channels; and (c) how to use these modulators so identified to modulate cellular potassium concentration and therefore cellular function in relevant tissue. Because many currently marketed drugs treat a wide variety of diseases or conditions by targeting ion channels, one skilled in the art would believe that the identification of a new potassium channel is useful for developing new therapeutics. The credibility of the asserted utility is established by way of a declaration under 37 C.F.R. §1.132 by Dr. Douglas Krafte.

3. Dr. Krafte's Declaration Supports the Contention of a Specific, Substantial, and Credible Asserted Utility

To bolster the above stated position, Appellant further offers a declaration under 37 C.F.R. §1.132 by Dr. Douglas Krafte (filed with Appellant's response of April 27, 2007, a copy is presented in the appendix of this appeal brief), where Dr. Krafte attests that, given the general state of the art and the disclosure of this application, one of

ordinary skill in the art would find the asserted utility specific, substantial, and credible. Specifically, Dr. Krafte states in paragraphs 6 and 7 of the declaration that,

> Several subfamilies of the Kv potassium channel family have previously been identified. These potassium channels are indicated in signal transduction during various biological processes such as neuronal integration, cardiac pacemaking, muscle contraction, hormone secretion, cell volume regulation, lymphocyte differentiation, and cell proliferation. Given this knowledge and the specific expression of Kv10.1 in the CNS, male reproductive organs, and retina, one of ordinary skill in the art would recognize the Kv10 channel as a therapeutic target for treating CNS or vision disorders or for regulating male infertility. In support of this statement, there is a recent publication describing mutations in the Kv10.1 gene (KCNV2) that are responsible for a specific vision disorder, which is characterized by reduced visual acuity, photoaversion, night blindness, and abnormal color vision (Wu et al., 2006 Am. J. Hum. Genet. 79: 574-579, attached as Exhibit B). The identification of human Kv10.1 coding sequence makes it possible to screen for activators and inhibitors of Kv10 potassium channels. Because such activators or inhibitors can be used for treating abnormalities in the relevant tissues (such as epilepsy, impaired vision, and male infertility), the present invention has a specific and real-world use. A further example of targeting potassium channels for therapeutic purpose is KCNQ2. Loss of function mutations of KCNQ2 have been shown to cause a form of epilepsy (Singh et al., 1998 Nat. Genetics 18: 25-29, attached as Exhibit C) and the KCNQ2 channels have been targets for drug discovery programs for a number of years (see, e.g., Wickenden et al., 2004 Expert Opin. Ther. Patents 14(4): 1-13, attached as Exhibit D).
>
> It is well known in the art that once an ion channel has been identified, modulators of this ion channel can be routinely identified based on the coding sequence of the ion channel, functional expression, and a method for activation of the channel. The present application provides nucleic acid sequences encoding human Kv10.1 polypeptides as well as methods for activating a Kv10 potassium channel, one of ordinary skill in the art can thus conduct routine testing to

> identify activators or inhibitors of a Kv10 potassium channel useful for modulating signal transduction in the cells where this potassium channel is present (e.g., the brain, spinal cord, prostate, testis, and retina), and therefore useful for treating neurological disorders and vision problems, or for modulating male fertility.

Thus, besides the presumption of patentable utility arising from the assertion of utility, Appellant has provided a declaration by a skilled artisan to further support the contention that the asserted utility of this invention is specific, substantial, and credible.

4. The Examiner Has Not Provided Objective Reasons Sufficient to Rebut Dr. Krafte's Declaration

In the Final Office Action of June 11, 2007, the Examiner sustains the rejection of the pending claims for alleged lack of utility, stating that the asserted utility for the claimed invention is neither specific nor substantial. Specifically, the Examiner argues that because the potassium channel family represents a board class of molecules involved in a variety of physiological processes, "the utility of the Kv10.1 channel cannot be immediately recognized as specific and substantial [and] credible by virtue of belonging to a class of molecules with a specific and well-established utility because the potassium channels do not have common physiological function." See the last paragraph on page 4 of the Final Office Action of June 11, 2007. Appellant contends that the Examiner has not provided objective reasons that are proper or sufficient to rebut the presumption of proper utility under 35 U.S.C. §101, especially in view of Dr. Krafts's declaration.

i. Appellant Does Not Have the Initial Burden to Provide Evidence of Utility

As indicated in the first paragraph on page 5 of the Final Office Action, one reason for sustaining the utility rejection is that no evidence other than Kv10.1 channel tissue distribution was provided by Appellant to substantiate the asserted utility, for example, that the Kv10.1 potassium channels are involved in any disease or disorder.

Appellant contends that a utility rejection raised in this manner is inconsistent with the proper practice described in the MPEP, which places the initial burden on the Examiner, not a patent applicant, to provide evidence to support a factual conclusion of the credibility of an asserted utility. In fact, MPEP §2107.02 III.B. specifically cautions Office personnel that, once an assertion of a particular utility is made, "that assertion cannot simply be dismissed ..... as 'wrong,' even when there may be reason to believe the assertion is not entirely accurate." Instead, the Examiner must provide an explanation setting forth the reasoning used in concluding that the asserted utility is not credible; support for factual findings relied upon in reaching the conclusion; and an evaluation of all relevant evidence of record, including utilities taught in the closest prior art. MPEP §2107.02 IV.

ii. The Examiner Has Not Offered Sufficient Objective Reasons to Overcome the Presumption of Patentable Utility

Although without the initial burden, Appellant has nonetheless offered as evidence Dr. Krafte's Rule 132 declaration to establish that the asserted utility is specific, substantial, and credible to an ordinarily skilled artisan. In response, the Examiner argues that, unless a specific disease or disorder is connected to Kv10.1, identifying the Kv10.1 polypeptide as a potassium channel subunit is insufficient to establish a specific or substantial utility, because there is much diversity in the physiological functions of potassium channels and also in the etiologies of disorders involving CNS, vision, or male fertility. See pages 4-5 of the Final Office Action. Other than relying on the references cited by Dr. Krafte in his declaration, the Examiner cites no further reference to support her contention.

Appellant contends that the purported diversity in potassium channel functions and etiologies of CNS, vision, or male fertility disorders does not amount to sufficient reasons to overcome the presumption of patentable utility. Indeed, such diversity does not in any way contradict the utility asserted in the specification, *i.e.*, a

Kv10.1 channel can be used to identify its modulators, which in turn can be used for treating CNS, vision, or male fertility disorders. Instead of providing any evidence or objective reason that clearly contradicts the asserted utility, the Examiner continues questioning and doubting the asserted utility, apparently still not believing that Kv10.1 modulators can be used for treating CNS, vision, or male fertility disorders. Without sufficient reasons articulated based on specific facts, however, the Examiner is required by the MPEP to accept the asserted utility.

Moreover, in paragraph 8 of his declaration, Dr. Krafte explains how an ion channel can be targeted in a therapeutic strategy without being the causation of a disease or condition,

> There are known instances where modulation of an ion channel is useful for treating a specific disease even though the channel itself may not cause the disease. For example, hypertension can be caused by a variety of illnesses such as renal disease and diabetes. Among the treatment strategies for hypertension is the use of drugs such as calcium channel blockers to relax the vasculature. Relaxing the vasculature to reduce blood pressure by blocking a calcium channel is useful and effective, even if the original cause of the hypertension is unrelated to the calcium channel itself. Similarly, it is perfectly reasonable to expect that the targeting of a Kv10 channel, a voltage-gated potassium channel expressed at a high level in the CNS, ocular tissue, and male reproductive system, is an appropriate strategy for treating disorders in the CNS or vision, or conditions related to male fertility, whether or not such abnormality is directly caused by altered Kv10 activity. Thus, the disclosure of the present application is sufficient to establish the utility of Kv10.1.

It is therefore established from the perspective of an artisan why a Kv10.1 potassium channel need not be the direct cause of a disease to serve as a therapeutic target for the condition.

In summary, when considered together with Appellant's arguments and particularly evidence submitted in the form of Dr. Krafte's declaration, the Examiner's

arguments are simply insufficient to rebut the presumption of patentable utility under 35 U.S.C. §101. As such, the utility rejection cannot be properly maintained.

5. Claims Drawn to Nucleic Acids Encoding Fully Characterized Proteins Meet the Utility Requirement under 35 U.S.C. §101

Appellant also contends that the asserted utility of this invention satisfies the utility requirement under 35 U.S.C. §101 in accordance with the standards promulgated by the USPTO. The claimed Kv10 polypeptides are fully characterized both structurally and functionally. The Kv10 polypeptides are defined by shared structural features, *e.g.*, they comprise an amino acid sequence that has at least 90% sequence identity to a reference sequence (SEQ ID NO:3), and shared functional features, *e.g.*, they are an alpha subunit of a voltage-gated Kv potassium channel.

According to *the Revised Interim Utility Guidelines Training Materials* ("*the Utility Guidelines*"), a characterized protein has sufficient utility for patentability. This standard is made evident from Example 8 of *the Utility Guidelines*. In Example 8, a compound A is disclosed to inhibit enzyme XYZ, a well known enzyme, *in vitro*. The specification states that the compound A can be used to treat diseases caused or exacerbated by enzyme XYZ. No such diseases are named. Claim 1 is directed to compound A. Claim 2 is directed to a method of treating a disease caused or exacerbated by enzyme XYZ consisting of administering an effective amount of compound A to a patient. In the subsequent analysis, claim 2 is deemed to be insufficiently supported by a real world context of use. This is because neither the specification nor the art of record discloses any disease or conditions caused or exacerbated by enzyme XYZ and therefore, the asserted utility is seen as a method of treating an unspecified and undisclosed disease or condition, which does not define a "real world" context of use. Claim 1, however, is regarded as having utility because claim 1 is directed to a compound that inhibits an enzyme and enzymes have well established utility in the art, *i.e.*, catalyzing certain reactions.

The present application can be analogized to this example. The present application claims polypeptides that are voltage-gated Kv potassium channel alpha subunits, which are analogous to compound A that inhibits enzyme XYZ. The specification indicates that Kv10 channels are likely involved in modulating cell excitability in certain tissues and organs such as the central nervous system (CNS) (*e.g.*, brain), male reproductive organs, and retina. Thus, the ion channels can be used as targets for treating CNS or vision disorders or for regulating male infertility. In Example 8 of the Utility Guidelines, claim 1 directed to compound A is found to have utility even though there is no disclosure of specified disease that to be treated. Accordingly, even if the Examiner is not convinced, despite the disclosure by the present specification and Dr. Krafte's declaration, that Kv10 channels are involved in regulation of cell excitability in certain tissues, a claim directed to compound A, *i.e.*, the polypeptide of an alpha subunit of a Kv10 potassium channel, has sufficient utility for patentability. The utility resides in the fact that the claimed polypeptide is a voltage-gated potassium channel alpha subunit, which potassium channels, like enzymes, have a well-established utility in the art: adjusting the passage of K^+ according to varying physiological conditions.

Analysis of pending claims according to *the Utility Guidelines* therefore further supports Appellant's position that the rejection for lack of utility is improper.

6. The Utility Rejection Contradicts the Allowance of the Parent Application

Lastly, Appellant notes that USSN 09/833,466, of which this application is a division, has already issued as U.S. Patent No. 6,727,353. Considering the fact that the two applications have the same specification, one claiming the Kv10 polynucleotide and the other the Kv10 polypeptide, the utility rejection in this application is in direct contradiction with the patentable utility apparently recognized in the parent application. To sustain this rejection would create a significant inconsistency in the PTO's treatment of this invention.

7. The Utility Rejection Is Based on Erroneous Reasoning

In the Final Office Action of June 11, 2007, the Examiner discusses several specific reasons for sustaining the utility rejection. First, the Examiner alleges that the asserted utility is not specific because no individual disease is named as treatable by a Kv10.1 channel modulator (see, *e.g.*, pages 5-6 of the Final Office Action); second, the Examiner argues that the fact pattern in the present case is distinct and cannot be analogized to Example 8 of *the Utility Guidelines* (see, *e.g.*, pages 6-7 of the Final Office Action); third, the Examiner contends that post-filing publications such as those provided as Exhibits of Dr. Krafte's declaration cannot be relied on to establish utility (see, *e.g.*, page 7 of the Final Office Action). Appellant respectfully disagrees with the Examiner on all these points.

For the first point, the Examiner has inappropriately over-emphasized the identity of a treatable condition in considering the utility of the claimed invention, which is a Kv10 potassium channel polypeptide, not a Kv10 channel modulator. Although the utility of a Kv10 channel protein is asserted through the use of its modulator, Appellant does not believe that the same set requirements for should apply insofar as patentability is concerned regarding, for example, utility, enablement, and written description. The Examiner's basis for sustaining the utility rejection is therefore invalid.

Second, the Examiner makes a distinction between an enzyme of Example 8 of *the Utility Guidelines* and a Kv10 channel of this invention, apparently taking the position that because each enzyme has a specific substrate and therefore a specific activity, whereas a Kv10 channel lacks an analogous specific activity because it is among many voltage-gated potassium channels that perform a similar function of regulating potassium ion passage. This approach of determining whether a specific activity exists for a protein is arbitrary and leads to erroneous conclusions. To use an example to illustrate the logical flaw in the Examiner's reasoning, one may consider a DNA polymerase belonging to a large variety of different types that all perform similar functions in synthesizing DNA strands. According to the Examiner's view, the

polymerase would be without a specific activity (and utility) due to the existence of like polymerases. Yet also according to the Examiner's view, the polymerase should be deemed to have a specific activity (and utility) because it is an enzyme. It is Appellant's position that the essence of Example 8 of *the Utility Guidelines* should be properly summarized as follows: if a protein has a clearly established biological function, then the protein, its encoding polynucleotide sequence, or its inhibitor has utility. The Kv10 potassium channel subunit of this invention is exactly a protein of this nature.

Third, the Examiner's refusal to consider post-filing publications for the sole purpose of confirming a utility already clearly asserted in the specification is wrong. As Appellant has pointed out in the earlier sections of this brief, this application clearly presents an asserted utility of the claimed invention: Kv10 channels can be used for identifying Kv10 channel modulators, which in turn can be used for therapeutic agents for treating CNS, vision, or male fertility disorders. None of the post-filing references are cited to establish a patentable utility not previously set forth; these references are used only to **confirm** a utility that is already fully described and clearly asserted in the specification. The Examiner's treatment of post-filing publications that are cited for the sole purpose of confirming previously asserted utility is directly and completely contrary to the USPTO's long-standing practice.

In all, Appellant does not believe that there exist sound reasons for sustaining the utility rejection.

8. Summary

In light of the foregoing discussion, Appellant believes that the utility rejection under 35 U.S.C. §101 is improper and respectfully requests its withdrawal.

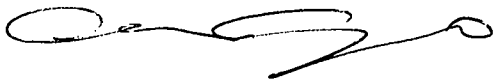
B. The Rejection for Lack of Enablement Is Improper

The Examiner has further sustained the rejection of claims 12-14 and 16-18 under 35 U.S.C. §112, first paragraph, alleging that the claimed invention is not

sufficiently enabled because the invention allegedly lacks a patentable utility. As discussed in the last section, a patentable utility of the claimed invention has been established. Thus, the enablement rejection based on lack of utility is improper and should be withdrawn.

In view of the foregoing, Appellant believes that all claims now pending in this Application are in condition for allowance.

Respectfully submitted,



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X. RELATED PROCEEDINGS APPENDIX

None.

IX. EVIDENCE APPENDIX

This appendix contains a copy of a declaration by Dr. Douglas Krafte with all of its exhibits, which was submitted on April 27, 2007, pursuant to 37 C.F.R. §1.132, and entered into the record as indicated on page 3 of the Final Office Action mailed June 11, 2007.

VIII. CLAIMS APPENDIX

12. An isolated polypeptide comprising an alpha subunit of a Kv potassium channel, the polypeptide:

(i) forming, with at least one additional Kv alpha subunit, a Kv potassium channel having the characteristic of voltage-gating; and

(ii) comprising an amino acid sequence having at least 90% sequence identity to SEQ ID NO:3.

13. The polypeptide of claim 12, wherein the amino acid sequence has at least 95% sequence identity to SEQ ID NO:3.

14. The polypeptide of claim 12, wherein the polypeptide has a molecular weight of between about 58 kD to about 68 kD.

16. The polypeptide of claim 12, wherein the polypeptide has an amino acid sequence of SEQ ID NO:3.

17. The polypeptide of claim 12, wherein the polypeptide comprises an alpha subunit of a homomeric potassium channel.

18. The polypeptide of claim 12, which comprises an alpha subunit of a heteromeric potassium channel.